

U.S. Application No.: NEW
PRELIMINARY AMENDMENT

Attorney Docket: 2368.172

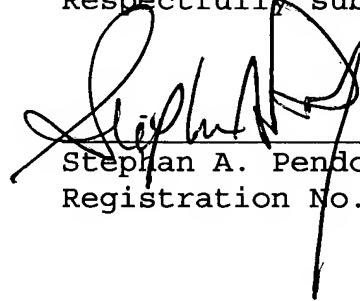
REMARKS

The claims have been amended in order to eliminate multiple dependent claims and claims improperly depending from multiple dependent claims, and to otherwise conform the claims to U.S. practice. Care has been taken to ensure that no new matter is added to the text.

Paragraphs [0002], [0006] and [0007] have been amended, to remove references to the Claims in the specification. Applicants are submitting herewith a substituted Specification. Care has been taken to ensure that no new matter has been added.

Entry and favorable consideration prior to consideration are respectfully requested.

Respectfully submitted,



Stephan A. Pendorf
Registration No. 32,665

PENDORF & CUTLIFF
5111 Memorial Highway
Tampa, Florida 33634-7356
(813) 886-6085

Date: **November 28, 2005**

U.S. Application No.: NEW
PRELIMINARY AMENDMENT

IAP16 Rec'd PCT/PTO 28 NOV 2005

Attorney Docket: 2368.172

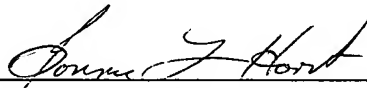
EXPRESS MAIL CERTIFICATE

"EXPRESS MAIL" MAILING LABEL NUMBER: EV687310415US

DATE OF DEPOSIT: November 28, 2005

I HEREBY CERTIFY that the foregoing Preliminary Amendment and a stamped receipt post card are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated with sufficient postage and is addressed: **ATTN: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account Number 16-0877.



Bonnie L. Horst

10/558442

IAP16 Rec'd PCT/PTO 28 NOV 2005

MARKED UP VERSION OF
SPECIFICATION INDICATING
ADDITIONS AND DELETIONS

"EXPRESS MAIL" LABEL NO.: EV 6873104150 S
I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE
UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO
ADDRESSEE" SERVICE UNDER 37 CFR. 1.10 IN AN ENVELOPE ADDRESSED
TO: THE COMMISSIONER OF PATENTS, P.O. BOX 1450, ALEXANDRIA, VA
22313-1450, ON THIS DATE. THE COMMISSIONER IS HEREBY AUTHORIZED
TO CHARGE ANY FEES ARISING HEREFROM AT ANY TIME TO DEPOSIT
ACCOUNT 16-0877.

11/28/05
DATE

Donna J. Howard
SIGNATURE

IAP16 Rec'd PCT/PTO 28 NOV 2009

INSTRUMENT FOR THE UNIPOLAR ABLATION OF HEART TISSUE

Cross Reference To Related Application

[0001] This application is a national stage of PCT/EP2004/005415 filed May 19, 2004 and based upon DE 103 23 566.3 filed May 26, 2003 under the International Convention.

BACKGROUND OF THE INVENTION

Field of the invention

[0002] The invention relates to an instrument for the unipolar ablation of heart tissue ~~according to the pre-characterizing portion of claim 1.~~

Related Art of the invention

[0003] In surgical heart therapy electrical ablation is utilized, e.g. for the treatment of arrhythmia. Electrical energy, preferably in form of high frequency current is conducted into the region of the heart tissue causing the arrhythmia, particularly the atrium, to selectively damage the tissue in order to eliminate the cause of the arrhythmia. For this, instruments with bipolar and with unipolar supply of HF-energy are known. Further, it is known that a rinsing liquid may flow through the instrument and be discharged at the distal end in the region of the electrode. The rinsing liquid, e.g. a Ringer solution or other electrolytic liquid, serves for cooling and, as the case may be, for improvement of the electrical conductivity between the electrode and the tissue.

[0004] In US 5,782,760 an instrument of the previously mentioned kind is disclosed. This instrument is introduced into the heart of the patient through a blood vessel. Here the tube, which conducts the electrical energy and the rinsing liquid to the distal end, is

constituted as a flexible catheter. In instruments which are introduced by means of an invasive surgical intervention through the thorax into the heart, the tube is constituted as a rigid shaft.

SUMMARY OF THE INVENTION

[0005] The objective of the invention is to create an instrument of the above mentioned kind which is cost efficient and ergonomically advantageous.

[0006] ~~The objective is accomplished according to the invention by an instrument according to the characterizing portion of claim 1.~~

[0007] ~~Advantageous embodiments of the invention are given in the dependent claims.~~

[0008] The instrument for the unipolar ablation of heart tissue according to the invention is introduced through the opened thorax or a micro invasive cut into the atrium of the heart. The instrument features a rigid shaft tube which carries on its distal end a detachable electrode. The shaft tube with its handle on the proximal end, the proximal electrical connection and the proximal connection for the rinsing liquid is designed as a re-usable part which can be disinfected and sterilized repetitively. The electrode is easily exchangeable, preferably via a plug-in connection, so that the electrode can be constructed as a single-use disposable. Thus the instrument is cost efficient for this use.

[0009] In an especially advantageous embodiment the electrode is snapped onto the distal end of the shaft tube by means of a detent,

providing for a simple exchange of the electrode without the necessity for special tools or special technical knowledge.

[00010] The handle preferably consists of plastic and is molded directly onto the proximal end of the shaft tube, which on one hand provides an ergonomically advantageous handling of the instrument and on the other hand results in a reduction of the production cost.

Brief Description of the Drawings

[00011] An advantageous embodiment of the invention will be described in detail in the examples below. They show:

- Fig. 1 an overall view of the instrument,
- Fig. 2 the distal end of the instrument in an axial cross-section along the line A-A in Fig. 1,
- Fig. 3 the distal end of the shaft tube in axial cross-section,
- Fig. 4 the distal electrode in a side view and
- Fig. 5 an electrode ferrule in axial cross-section.

Detailed Description of the Invention

[00012] Fig.1 shows the overall instrument for the unipolar ablation of heart tissue approximately in a 1:1 scale. The instrument features a shaft 10 with a handle 12 on its proximal end. On the distal end of the shaft 10 an electrode 14 is located. At the proximal end of the handle 12 a rinse connection 16 is located axially aligned along the centerline of the shaft 10 which is constituted as a hose connection to connect to a hose for the rinsing fluid. Also at the proximal end is an electric connection 18 which is preferably constituted as a plug and socket connection for the high frequency power supply.

[00013] The handle 12 encloses the shaft 10 cylindrically like a penholder handle. The distal end of the shaft 10 with the electrode 14 is angled between approximately 30° and 45° with respect to the centerline of the shaft 10. Thus, it provides for ergonomic handling and enables unerring placement of the electrode tip.

[00014] The shaft 10 is constituted by an electrically conducting rigid metallic shaft tube 20 which over its entire length is covered by an electrically insulating cladding 22 made from plastic. The handle 12 preferably consists of the same plastic material such that the handle 12 can be molded around the shaft tube 20 as one piece together with the cladding 22.

[00015] The construction of the distal end of the instrument is shown in detail in Figs.2 through 3.

[00016] As shown in Figs.2 and 3 the insulating cladding 22 ends before the distal end of the shaft tube 20, so that a distal end section 24 of the shaft tube 20 remains uncovered by the cladding 22. In this end section 24 directly in front of the distal end of the cladding 22 a radial groove 26 is machined into the outer circumflex of the shaft tube 20.

[00017] As shown in Fig.2 and 4 the electrode 14 is constituted by an essentially cylindrical body made of an electrically conducting material. The electrode 14 is pushed with its proximal end section 28 into the distal end of the shaft tube 20, in which the outer diameter of said end section 28 equals the inner diameter of the shaft tube 20, such that the electrode 14 can be introduced into the shaft tube 20 with a tight fit. The electrode 14 is

stopped with its external collar 30 on the distal end of the shaft tube 20. The outer diameter of the external collar equals essentially the outer diameter of the end section 24 of the shaft tube 20. The distal end of the electrode 14 which constitutes the distal end of the instrument is monolithic and domed in distal direction. From the proximal end a blind hole 32 coaxially leads into the electrode 14. The blind hole 32 stretches in distal direction beyond the external collar 30. At the distal end of the blind hole 32 four discharge openings 34 with an offset of 90° to each other stretch radially from the circumflex of the electrode 14 into the blind hole 32. The discharge openings 34 meet at their outer end with a shared circumferential recess 36 of the electrode 14.

[00018] As shown in Fig.2 and 5 an electrode ferrule 38 made of electrically insulating plastic is pushed from the distal end over the electrode 14 which sits in the shaft tube 20. When assembled (Fig.2) the electrode ferrule 38 axially overlaps with its proximal end the distal end of the insulating cladding 22. Thus the electrode ferrule 38 seamlessly continues the electrical insulation of the cladding 22. The electrode ferrule 38 features in its proximal end region an internal detent 40 which snaps into the radial groove 26 of the shaft tube 20 when the electrode ferrule 38 is assembled. The detent 40 may be constituted from a single punctiform cam, multiple angled and staggered cams or a bead covering a pitch circle.

[00019] In the distal end section the electrode ferrule 38 features an internal collar 42. When the electrode ferrule 38 is assembled, the internal collar 42 axially contacts and stops at the external collar 30 of the electrode 14 whereby the electrode 14 is

fixed in the distal end of the shaft tube 20 and the electrode 14, by means of its external collar 30, maintains an electrically conducting path to the distal end of the shaft tube 20. Thus a reliable electrical contact between the shaft tube 20 and the electrode 14 is guaranteed. At the distal end of the electrode ferrule 38, before the internal collar 42, the inner diameter of the electrode ferrule 38 is larger than the outer diameter of the electrode 14, so that between the electrode 14 and the electrode ferrule 38 an annular gap 44 remains open in the distal direction. The discharge openings 34 meet with this annular gap 44. The electrode ferrule 38 which is pushed and snapped onto the shaft tube 20 ends distally in a radially enlarged flange 46. The distal end of the electrode 14 protrudes the flange 46 in the distal direction, so that the flange 46 serves as a stop, limiting the insertion depth of the tip of the electrode 14 into the tissue being treated.

[00020] The proximal electrical connection 18 of the instrument is connected to a high frequency power supply which is not shown. The high frequency current flows from the electrical connection 18 through the shaft tube 20 to the electrode 14. With the electrode's 14 bare distal tip the unipolar current is applied to the treated tissue. With exception of the bare electrode tip, the shaft tube 20 and the electrode 14 are completely electrically insulated on their outside through the handle 12, the cladding 22 and the electrode ferrule 38.

[00021] Through the proximal rinse connection 16 a rinsing liquid is introduced. The rinsing liquid flows through the lumen of the shaft tube 20 into the blind hole 32 of the electrode 14 and escapes through the radial discharge openings 34. Through the

circumferential recess 36 and the annular gap 44 a uniform flow around the tip of the electrode 14 is achieved.

Reference numeral list

10	shaft
12	handle
14	electrode
16	rinse connection
18	electric connection
20	shaft tube
22	cladding
24	end section of 20
26	radial groove
28	proximal end section of 14
30	external collar of 14
32	blind hole
34	discharge opening
36	circumferential recess
38	electrode ferrule
40	detent
42	internal collar
44	annular gap
46	flange